

**FINDING OF NO SIGNIFICANT IMPACT
FOR**

Food Additive Petition 9A4652, submitted by the Procter & Gamble Company, to amend the food additive regulations to provide for the safe use of olestra in place of fats and oils in prepackaged, unpopped popcorn kernels that are ready to heat.

The Chemistry and Environmental Review Team, Division of Product Policy, Center for Food Safety and Applied Nutrition, has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment for the subject petition and information in an environmental assessment and Finding of No Significant Impact prepared for Food Additive Petition 7A3997.

Prepared by: *Jeanette Glover Glew*
Jeanette Glover Glew, Environmental Scientist
Chemistry and Environmental Review Team
Division of Product Policy

Date: September 20, 1999

Approved by: *Layla I. Batarseh*
Layla I. Batarseh, Ph.D., Team Leader
Chemistry and Environmental Review Team
Division of Product Policy

Date: September 20, 1999

died." should read "and nearly 1,000 people died."

On page 9046, 1st column, heading for #5: Should read "What if there is a moderate or severe reaction?" (not problem)

All other information and requirements of the notice remain the same.

Dated: March 31, 1999.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-8410 Filed 4-5-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-0720]

Arakawa Chemical Industries, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Arakawa Chemical Industries, Ltd. has filed a petition proposing that the food additive regulations be amended to expand the safe use of hydrogenated aromatic petroleum hydrocarbon resins for use in blends with polymers intended for contact with food.

DATES: Written comments on the petitioner's environmental assessment by May 6, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4653) has been filed by Arakawa Chemical Industries, Ltd., c/o Keller and Heckman, LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in 21 CFR part 178—Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers and in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to expand

the safe use of hydrogenated aromatic petroleum hydrocarbon resins, for use in blends with polymers intended for contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before May 6, 1999, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: March 22, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-8441 Filed 4-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-0719]

The Procter & Gamble Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that The Procter & Gamble Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of olestra in

place of fats and oils in prepackaged, unpopped popcorn kernels that are ready-to-heat.

DATES: Written comments on the petitioner's environmental assessment by May 6, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3090.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9A4652) has been filed by The Procter & Gamble Co., Winton Hill Technical Center, 6071 Center Hill Ave., Cincinnati, OH 45224. The petition proposes to amend the food additive regulations in § 172.867 *Olestra* (21 CFR 172.867) to provide for the safe use of olestra in place of fats and oils in prepackaged, unpopped popcorn kernels that are ready-to-heat.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before May 6, 1999, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: March 22, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-8442 Filed 4-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P-1121]

Grated Parmesan Cheese Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Kraft Foods, Inc., to market test a product designated as "100% Grated Parmesan Cheese" that deviates from the U.S. standards of identity for parmesan cheese and grated cheeses. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility, in support of a petition to amend the standard of identity for parmesan cheese.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than July 6, 1999.

FOR FURTHER INFORMATION CONTACT:

Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093.

The permit covers 86 million pounds of interstate marketing tests products identified as "grated parmesan cheese" that deviate from the U.S. standard of identity for parmesan cheese (21 CFR 133.165) and grated cheeses (21 CFR 133.146) in that the product is formulated by using a different enzyme technology that fully cures the cheese in 6 months rather than 10 months. The

test product meets all the requirements of the standards with the exception of this deviation. Because test preferences vary by area, along with social and environmental differences, the purpose of this permit is to test the product throughout the United States.

Under this temporary permit, the parmesan cheese will be test marketed as grated parmesan cheese. The test product will bear the name "100% Grated Parmesan Cheese."

This permit provides for the temporary marketing of 86 million pounds of grated parmesan cheese in retail containers of various sizes. The test product will be manufactured at Kraft Foods, Inc., 10800 Avenue 184, Tulare, CA 93274. The product will then be shipped to Kraft Foods Inc., 1007 Town Line Rd., Wausau, WI 54401, where it is aged, grated, and packaged for distribution. The product will be distributed throughout the United States.

The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101.

This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than July 6, 1999.

Dated: March 29, 1999.

Kenneth J. Falci,

Acting Director, Office of Food Labeling, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-8440 Filed 4-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96G-0096]

The Flax Council of Canada; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 5G0416) proposing to affirm that the use of low linolenic acid flaxseed oil is generally recognized as safe (GRAS) as a food oil.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety

and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3103.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of March 27, 1996 (61 FR 13505), FDA announced that a petition (GRASP 5G0416) had been filed by the Flax Council of Canada, 465-167 Lombard Ave., Winnipeg, MB R3B 0T6, Canada. This petition proposed that the use of low linolenic acid flaxseed oil as a food oil be affirmed as GRAS.

The Flax Council of Canada has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 17, 1999.

Eugene C. Coleman,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-8443 Filed 4-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0557]

"Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans." The guidance document is being issued in response to public comments and recent interest among clinical investigators in using nonhuman primate xenografts in the near future. The document is intended to provide guidance on nonhuman primate xenotransplantation in humans.

DATES: Written comments may be submitted at any time, however, comments should be submitted by July 6, 1999, to ensure adequate consideration in preparation of a revised document, if warranted. The agency is soliciting public comment but is implementing this guidance document immediately because of the public health concerns related to the use of live cells, tissues, and organs from nonhuman primate xenografts in humans.

FINDING OF NO SIGNIFICANT IMPACT

FOR

Food Additive Petition 7A3997, submitted by The Procter & Gamble Company, proposing the issuance of a food additive regulation providing for the safe use of sucrose esterified with medium and long chain fatty acids (olestra) as a fat replacer in the preparation of savory snacks.

The Environmental Impact Staff, Center for Food Safety and Applied Nutrition, has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by Procter & Gamble in an environmental assessment (EA) prepared using the format described in 21 *CFR* 25.31a(a) and on the following:

Adverse environmental effects are not expected to result from the manufacture of olestra or from the production or consumption of savory snacks containing olestra. A chart summarizing substances expected to be emitted to the environment as a result of olestra manufacture, snack production, and consumption is included as Table 6.1 of the EA, and a flowchart illustrating the fate of olestra is included as Table 6.2 of the EA. Information provided by Procter & Gamble on the fate and potential environmental effects of olestra, detailed below, supports the conclusion that there will be no significant environmental impacts from its manufacture, use, and disposal.

I. Introductions from Olestra Manufacturing

Adverse environmental effects are not expected to result from the manufacture of olestra. A list of substances expected to be emitted during the manufacture of olestra is included as Table 6-3 of the EA, and estimated quantities of materials expected to enter the environment as a result of the manufacture of olestra are included as Table 6-4 of the EA.

- A. Procter & Gamble states that the manufacturing plant is currently in compliance with all applicable permits and environmental ordinances. Procter & Gamble further states that manufacture of olestra will be carried out in compliance with all Federal, State, and local regulations and will include the use of collection and containment devices to conform to these regulations. Control devices include bag house dust collectors, cyclonic separators, surface condensers, scrubbers, gravity separators, the local publicly owned treatment works (POTW), and off-site incineration equipment. (See format item 6.a.i.)
- B. Dust particles that may potentially be emitted to the atmosphere include sucrose, alkali metal salts, and adsorbent materials. Minimal amounts of these materials are expected to pass through control equipment. Volatile methanol emissions will be scrubbed, and Procter & Gamble states that air emission levels for

methanol will remain in compliance with permit requirements after approval of this action. (See EA format items 6.a.i. and 7.a.i.)

- C. The substances listed in part B above, along with alkali metal soaps of fatty acids, alkali metal sulfates, citrate salts, and the subject additive itself, could also enter the liquid wastestream. Water soluble components will be released in the industrial effluent to the local POTW where the wastewater will be treated and discharged. Most of the fatty acids, soaps, esters, and waste olestra will be collected, and these wastestreams will be hydrolyzed to fatty acids and sucrose for use in animal feeds. Approximately 90% of the olestra that remains in the liquid wastestream discharged to the POTW will be sorbed to solids and settle as sludge. Sewage sludge from the POTW that services the Ivorydale, Ohio, manufacturing site is burned for energy. The remaining 10% of nonsorbed olestra will be released in POTW effluent. (See EA format items 6.a.i. and 7.b.i.) The fate and potential effects of olestra emitted to the aquatic environment will be discussed more fully below in Section IV. C.
- D. Spent adsorbent materials saturated with olestra and methyl esters will be landfilled. Olestra is strongly immobile in soil, therefore it is not expected to leach from landfills. (See EA format items 6.a.i. and 7.c.i.)
- E. Procter & Gamble states that all manufacturing areas used for the production of olestra will be designed and operated to comply with applicable Occupational Health and Safety Administration (OSHA) regulations. Monitoring the work environment to determine occupational exposures will be carried out. (See EA format item 6.a.i.)
- F. Process and storage areas will be provided with spill protection to minimize the potential for releases to the terrestrial and aquatic environment. Accidental spill response plans will be in effect for potential spills during transport of olestra from the manufacturing plant to the snack production facility. (See EA format item 6.a.i.)

II. Introductions from Snack Production

Adverse environmental effects are not expected to result from the production of snacks containing olestra. Quantities of materials expected to be emitted during the production of olestra snacks are summarized in Table 6-5 of the EA. Procter & Gamble has used its Jackson, Tennessee, food plant as an example to illustrate the potential environmental impact of the use of olestra in snack production.

- A. Small amounts of waste oil from snack production will be emitted to the atmosphere as particulate matter. These emissions will be covered by applicable permits. (See EA format items 6.a.ii. and 7.a.ii.)

- B. Procter & Gamble states that spent frying oils from snack production, as well as fats captured from plant effluent, will be hydrolyzed to digestible fatty acids and sucrose and sold as animal feed. Additionally, Procter & Gamble postulates that some waste olestra could be burned as fuel. (See EA format item 6.a.ii.)
- C. The majority of fats remaining in wastewater plant effluent will be sorbed to solids and will become a component of sewage sludge. Sewage sludge containing olestra would most likely be applied as a soil amendment to agricultural land or it could potentially be landfilled. Fats remaining in the plant effluent wastewater will be released to receiving streams after treatment of the plant's wastewater. (See EA format items 6.a.ii, 7.b.ii, and 7.c.ii.) The fate and potential effects of olestra emitted to the aquatic environment and as a component of sewage sludge will be discussed more fully below in Section IV. C. and D.

III. Introductions from Snack Consumption

Adverse environmental effects are not expected to result as a consequence of consumer consumption of snacks containing olestra. Olestra will be introduced into the environment following snack consumption as a component of municipal or domestic (septic tank) wastewater. The concentration of olestra in municipal wastewater influent, effluent, receiving streams, sewage sludge, soil after sewage sludge application, and in septic tanks is calculated in Format item 6.b.i.-iv. The fate and potential effects of olestra emitted to wastewater treatment systems, the aquatic environment, and as a component of sewage sludge will be discussed more fully below in Section IV. A-D.

IV. Fate and Effect of Substances Released to the Environment

Procter & Gamble has provided studies documenting that releases in the wastestream from manufacturing, snack production, and consumption of olestra are not expected to have adverse effects upon wastewater treatment or exposed aquatic or terrestrial environments.

- A. Procter & Gamble performed studies on the effect of olestra on the functioning of wastewater treatment plants. Their studies on primary and secondary wastewater treatment processes (listed in Table 6-6 of the EA) demonstrate that olestra will not have an adverse effect on the effective functioning of wastewater treatment plants. Olestra increases settling of suspended sewage solids. Olestra is strongly associated with solids in the wastestream; Procter & Gamble submitted studies showing that approximately 23-64% of olestra is removed during primary treatment, and an additional 84% of the remaining olestra is removed following secondary treatment, closely corresponding to the removal of total suspended solids. The presence of olestra during activated sludge treatment did not disrupt the removal of chemical oxygen demand (COD), and anaerobic digestion was not inhibited at the olestra concentrations expected to be present in wastewater. (See EA format items 6.b.ii. and 8.b.iii.)

wastestream; Procter & Gamble submitted studies showing that approximately 23-64% of olestra is removed during primary treatment, and an additional 84% of the remaining olestra is removed following secondary treatment, closely corresponding to the removal of total suspended solids. The presence of olestra during activated sludge treatment did not disrupt the removal of chemical oxygen demand (COD), and anaerobic digestion was not inhibited at the olestra concentrations expected to be present in wastewater. (See EA format items 6.b.ii. and 8.b.iii.)

- B. Procter & Gamble's analysis establishes that consumption and excretion of olestra will not have an adverse effect upon the effective operation of domestic septic tanks. Olestra in human excreta should not increase the frequency of septic tank pumping or cause the failure of drain fields. (See EA format items 6.b.ii. and 8.b.iii.)
- C. Procter and Gamble provided studies on the fate and effects of olestra in aquatic and terrestrial systems (listed in Table 6-6 and summarized in Appendix 3 of the EA). The studies establish that, at the expected environmental concentrations, olestra would not have an adverse effect upon organisms exposed in the water column, in sediments, or in soil (following land application of sewage sludge). (See EA format items 7.b. and c. and 8.b.i. and ii.)
- D. Procter and Gamble concluded that olestra, as a component of sewage sludge, will not have an adverse effect on soil physical or chemical properties. It is expected to be a relatively small component of sludge, and tests demonstrate that it is not mobile and will not persist in soil. Olestra was found to be completely mineralized at a rate which will prevent accumulation in soil (half-life of 10 and 88 days, respectively, for liquid and solid olestra). (See EA format items 7.c. and 8.b.ii.4.)

In support of the EA, Procter & Gamble provided copies of written comments on the olestra environmental assessment from four individuals the firm identified as wastewater and environmental experts. These comments are attached to the EA.

Subsequent to submitting the EA, Procter & Gamble provided information on the degradation of olestra by microorganisms from activated sludge and other environments. This information was presented as a poster at an American Society of Microbiology Meeting and has been submitted for publication to the journal *Biodegradation*. Information contained in this draft article supports Procter & Gamble's conclusions in the EA about the fate of olestra in engineered and natural environments. The draft article is attached to the EA.

At the Food and Drug Administration's request, the Environmental Protection Agency (EPA) reviewed the information provided by Procter & Gamble on the potential effect

of olestra on wastewater treatment systems; exposed aquatic organisms, such as fish and sediment-dwelling animals; soil physical and chemical properties subsequent to sewage sludge application; and possible effects resulting from an accidental spill or treatment plant malfunction. EPA concluded that these issues had been satisfactorily addressed by Procter & Gamble in its EA for olestra, and did not raise any environmental objections to the use of olestra in savory snacks. EPA's conclusions are documented in the attached correspondence.

Prepared by: JS/ Date: August 3, 1995
Jeanette Glover Glew, Environmental Scientist
Environmental Impact Staff

Approved by: JS/ Date: August 3, 1995
Buzz L. Hoffmann, Ph.D., Chief
Environmental Impact Staff

5 Attachments:

1. EPA letter dated June 14, 1995, including attachments.
2. Memorandum of a telephone conversation between Jeanette G. Glew and Dr. Brown, dated June 20, 1995.
3. Memorandum of conference call from Jeanette G. Glew to Dr. Topper and Dr. Allgood, dated June 21, 1995.
4. Exhibit 1, from P&G's letter of June 23, 1995.
5. Memorandum of a telephone conversation between Jeanette G. Glew and Dr. Topper dated July 25, 1995.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

14 JUL 1995

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition
200 C St., SW, HSS-200
Food and Drug Administration
Department of Health & Human Services
Washington, D.C. 20204

JUN 19 1 15 PM '95

Dear Dr. Rulis:

In response to your request of April 11, 1995 the Environmental Protection Agency's (EPA) Office of Federal Activities (OFA) has reviewed the environmental assessment (EA) prepared for the Food and Drug Administration (FDA) in support of the petition for the use of olestra as a fat replacer in the production of savory snacks. In addition to review by OFA, EPA's Office of Water and Office of Research and Development have also reviewed the olestra EA and comments from those offices are enclosed.

The result of our review is that the questions originally raised about possible environmental impacts of olestra by the EPA Office of Water in 1987 have been answered in a satisfactory manner. In addition, the review by Dr. Brown raised a question concerning the rate at which olestra degrades in anoxic and/or anaerobic sediments. We suggest that you clarify this issue with Proctor and Gamble prior to your final decision to issue a Finding of No Significant Impact for the uses of olestra described in the EA which you submitted to us for review. The enclosure contains Dr. Brown's phone number. Please feel free to contact him directly if it will expedite the review process.

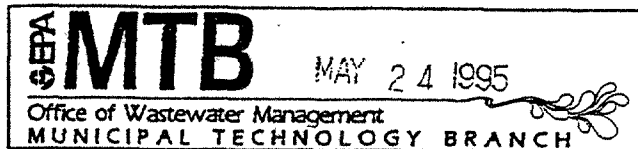
Should you have any further questions concerning the EPA review of the above-mentioned EA, please feel free to contact Dr. Martin D. Topper of my staff at (202) 260-5051.

Sincerely,

A handwritten signature in dark ink, appearing to read "Richard E. Sanderson", written in a cursive style.

Richard E. Sanderson
Director
Office of Federal Activities

Enclosures



MEMORANDUM

SUBJECT: Review of the Environmental Assessment of the Food Additive "Olestra".

FROM: James Wheeler, Environmental Engineer
Robert Bastian, Physical Scientist
Municipal Technology Branch (4204)

TO: Martin D. Topper, Ph.D.
NEPA Compliance Division (2252)

The Office of Wastewater Management (OWM) has primary responsibility for management of the National Permit Discharge Elimination System (NPDES). This program establishes discharge permit limits for all municipal and industrial wastewater treatment facilities. The NPDES program also establishes permit limits for the land application of wastewater treatment plant sludge (bio-solids). While not covered under the NPDES program, OWM also provides technical guidance and assistance on the design and operation of on-site treatment units, such as septic tanks and leach fields.

In a previous review, OWM raised several issues concerning the biodegradation and bioaccumulation of Olestra in aquatic and terrestrial ecosystems. OWM also raised issues about the treatability of Olestra by conventional wastewater treatment and digestion processes and by on-site septic systems. At your request, we have reviewed the revised Environmental Assessment from The Procter and Gamble Company, dated April 5, 1995. The results of our review are as follows.

The study indicates that Olestra will have little impact on conventional primary or secondary wastewater treatment processes. No significant difference in suspended solids removal or settling rates in either primary or secondary treatment processes were observed. In addition, Olestra appears to be compatible with conventional biological treatment processes and demonstrated no adverse impacts on activated sludge treatment or anaerobic digestion processes. It is also unlikely that Olestra will have any significant impact on any on-site septic systems, since it is readily biodegradable along with the other accumulated solids.

Although, more slowly degraded in the soil than in water, Olestra appears to have little impact on terrestrial ecosystems. The study indicates that Olestra appears to be compatible with natural biological treatment in the soil. No adverse toxicity impacts on plant, micro-organisms or invertebrates were observed. In addition, it appears unlikely that Olestra will have any adverse impacts on the physical or chemical properties of the soil. Direct impact on the soil properties are not expected because Olestra is nonionic and hydrophobic, similar to conventional bio-solids.

The study indicates that Olestra will have little impact on the aquatic environment, since it appears to be compatible with natural biological treatment in the water column and the sediments. Since no acute LC_{50} values were reached at the highest level tested, it was concluded that Olestra presents no hazard to aquatic life. In addition, exposure of aquatic species through ingestion rather than water dosing will not result in adverse effects, because deposition of a non-absorbed, non-toxic material is not an issue. Since Olestra does not display toxicity in water, it also would not be expected to display toxicity in the sediments. While no long term testing was conducted, Olestra did not demonstrate any acute toxicity, therefore, no chronic effects would be expected.

In conclusion, OWM believes that the revised Environmental Assessment has sufficiently addressed the concerns raised in our previous review. While we would feel more comfortable with the results of the assessment, if an actual acute LC_{50} level had been established and additional long term chronic toxicity testing had been performed, we do not believe that these studies are critical to the overall assessment. These studies might be suggested for future study.

Based on the information presented, the use of Olestra as a food additive in savory snack production does not appear to impose any significant adverse consequences on either natural environments or engineered treatment processes. The data would indicate that Olestra is non-toxic to aquatic and benthic organisms and will not bioaccumulate. Our overall conclusion is that the assessment establishes sufficient level of environmental safety and we would support the approval of Olestra as a food additive for use within the proposed ranges.

We appreciate the opportunity to review the revised Environmental Assessment and hope that our comments are helpful. Should you need any additional assistance or have any questions about our comments, please let me know. You can reach Bob at (202) 260-7378 or me at (202) 260-5827.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN - 8 1995

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: ORD Review of the Environmental Assessment for Olestra

FROM: Elaine Z. Francis, Ph.D. *Elaine Z. Francis*
Director, Toxics/Pesticides and Water Staff
Office of Research and Science Integration (8105)

TO: Martin D. Topper, Ph.D.
NEPA Compliance Division
Office of Enforcement and Compliance Assurance (2252)

Thank you for providing ORD the opportunity to review the environmental assessment prepared by Proctor and Gamble on Olestra. The assessment was sent to the National Risk Management Research Laboratory (NRMRL) in Cincinnati and the National Health and Environmental Effects Research Laboratory in Duluth. The laboratory in Duluth did not have any comments. As I indicated to you on the telephone, because Cincinnati is the home of Proctor and Gamble (P&G), several members of NRMRL own (P&G) stock or have other reasons for potential conflict of interest associated with reviewing the environmental assessment. The original intended reviewers had to excuse themselves from any role in the review for this reason. Therefore, to avoid any potential for conflict of interest Donald S. Brown, environmental engineer in the Water and Hazardous Waste Treatment Research Division, conducted the review for ORD. We appreciate the additional review time.

Dr. Brown's review focused on P&G's response to six questions raised during an August 1992 meeting. Therefore, he limited his review to four question (#3 - #6 in Dr. Allgood's letter) out of the six that pertain to wastewater treatment. Dr. Brown reviewed the specific portions of the environmental assessment (EA) that Dr. Allgood's letter referred to in response to the four wastewater questions. He also reviewed other portions of the EA that pertain specifically to wastewater treatment. He did not review the entire EA.

Based on Dr. Brown's review, ORD believes that overall, P&G has adequately responded to the wastewater treatment questions. We have a few comments specific to each question listed below.

Question #3. accidental spills and treatment plant malfunctions – The question relates to the impact of large amounts of olestra directly added to a waterway.

With regard to treatment plants, P&G did not estimate the amount of olestra that might be released during a malfunction. Because olestra appears to be highly associated with the wastewater solids, the worst case scenario would be a total wash out of the solids in the treatment plant. If it is conservatively assumed that olestra is completely adsorbed onto the wastewater solids and that no biodegradation occurs in the treatment plant, the concentration of olestra in an upset plant discharge can be estimated by the equation:

$$C_{od} = C_{oi} * (SRT/HRT) * (24 \text{ hrs/day})$$

where:

C_{od} = olestra concentration in the discharge from the aeration system (mg/L)

C_{oi} = olestra concentration in the aeration influent wastewater to aeration

HRT = hydraulic retention time in aeration basin (hours)

SRT = average solids retention time in aeration basin (days)

For a typical plant with primary treatment ($C_{od} = 3.8 \text{ mg/L}$, per P&G Exhibit #8), an SRT of 6 days and an HRT of 6 hours, the concentration in the discharge after upset is:

$$C_{od} = 3.8 \text{ mg/L} * (6 \text{ days}/6 \text{ hrs}) * (24 \text{ hrs/day}) = 91 \text{ mg/L}$$

For an extended aeration plant with no primary treatment ($C_{od} = 4.9 \text{ mg/L}$, per P&G Exhibit #2), a SRT of 40 Days and an HRT of 24 hours, the concentration is:

$$C_{od} = 4.9 \text{ mg/L} * (40 \text{ day}/24 \text{ hrs}) * (24 \text{ hrs/day}) = 196 \text{ mg/L}$$

These concentrations are below the aquatic acute no-observed effect level of >1000 mg/L reported in the EA. With a major malfunction of a wastewater treatment plant, the release of untreated wastes and any toxicant causing the malfunction could cause a major adverse environmental impact but that impact should not be caused by olestra. With its low acute toxicity and moderate rates of aerobic degradation, substantial acute toxicity or immediate oxygen demand from olestra should not occur. If the malfunction was due to a flooding event, the olestra concentration would be less because of the dilution effect of the flood water.

#4. fate of olestra if all solids are degraded — P&G's response at Format Item 8.b. i i 1.5 is appropriate. Biological wastewater treatment processes do not degrade all solids in the treatment plant, and in fact, produce biosolids in the treatment process. With olestra's high hydrophobicity, it will preferentially partition to the solids, leaving the treatment plant principally in the wasted biosolids.

Question #5. impact on direct treatment of manufacturing waste — P&G's discussions at Format Item 6. a. ii, are appropriate when the EPA recommended aerobic biological treatment is used and the projected olestra wastewater concentration levels are achieved.

Question #6. effect on soil properties — P&G did not present any data on soil chemical or physical properties as a function of olestra content. However, the general discussion at Format Item 8.b.iii.i is reasonable — at their projected levels, olestra should behave similarly to other organic materials in the biosolids.

If it is assumed that conservation of olestra added to the soil occurs, then it would build up to a soil concentration that could have significant effects on soil properties. However, if the half life of 88 days, based upon their limited data, is correct and a maximum soil concentration is 695 mg/Kg, then P&G's conclusions are reasonable.

In conclusion, at the projected productivity and consumption levels, olestra's: 1) lack of inhibition of microbial processes (aerobic and anaerobic); 2) lack of interference with solids removal; and 3) high hydrophobicity (i.e. strong preference to adsorb to wastewater solids); support the conclusion of minimal environmental impacts through wastewater treatment systems.

As a side note unrelated to the wastewater treatment issue, the very slow degradation of olestra under anaerobic condition is a concern. As noted by P&G, because of its preference to adsorb to solids, olestra in a treatment plant discharge will end up in the sediments which are typically anoxic or anaerobic. This issue does appear to have been addressed in portions of the EA which I did not review. The potential for chronic effects due to accumulation in anaerobic sediments needs to be reviewed by experts in that field.

If you have any questions regarding ORD's review and comments, please contact me at 260-0314 or contact Dr. Brown directly at (513) 569-7630 or brown.donald@epamail.epa.gov.

cc: E. Timothy Oppelt
Gil Veith
Donald S. Brown

MEMORANDUM OF TELEPHONE CONVERSATION

June 20, 1995

Between: Dr. Donald S. Brown
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Wastewater Treatment and Hazardous Waste Treatment Research
Environmental Protection Agency, Cincinnati
(513) 569-7630

and: Jeanette Glover Glew
FDA:CFSAN:OPA:DPMU:
Environmental Impact Staff

Subject: FAP 7A3997 - Olestra: EPA Review of the Environmental Assessment

I called Dr. Brown of the Environmental Protection Agency (EPA) to discuss the question he raised in his review of the environmental assessment of olestra on the fate and potential effect of olestra in anaerobic sediments. I asked him if an acceptable way to address his question would be to have a representative of Procter & Gamble and me confer with him by telephone. He said he didn't particularly want anyone to get back to him with an answer because that wasn't his area of expertise; he just wanted the people organizing the review for EPA to make sure someone else at EPA had addressed it. He said it wasn't his intention to have the question passed on to FDA or to Procter and Gamble. Dr. Brown said he was aware that his question was probably already addressed in the EA, but he only had reviewed the information having to do with wastewater processes.

JS!

Jeanette Glover Glew

MEMORANDUM OF CONFERENCE CALL

June 21, 1995

CONVERSANTS:

Environmental Protection Agency
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(202) 260-5051

Procter & Gamble
Dr. Greg Allgood
Section Head
Olestra Regulatory and Clinical Development
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Food and Drug Administration
Jeanette Glover Glew
Environmental Impact Staff
Division of Product Manufacture and Use
Center for Food Safety and Applied Nutrition

Subject: FAP 7A3997 - Olestra: EPA Review of the Environmental Assessment

I spoke with Dr. Topper and Dr. Allgood separately and jointly in regard to the remaining question raised by Dr. Brown of the Environmental Protection Agency (EPA) in his review of the olestra environmental assessment (EA): see memorandum of telephone conversation, June 20, 1995. Dr. Allgood pointed out that the review memorandum from the Office of Research and Development stated that Dr. Brown limited his review to questions #3-6 of Procter and Gamble's response to six questions raised by EPA. Dr. Allgood said that questions #1 and #2 of EPA's original questions specifically ask about the issue of olestra in sediments and potential benthic and aquatic toxicity. Procter & Gamble answered those questions in their response to EPA. Dr. Allgood and Dr. Topper noted that the EA had been reviewed by the National Health and Environmental Effects Research Laboratory in Duluth; the Duluth Lab is considered to have EPA's "water experts," and this group would have addressed that issue. The lab at Duluth did not have any comments on the EA. I asked Dr. Topper if he thought that EPA needed to do a further review to resolve the issue. He said he did not think that was necessary. Dr. Topper said that his review of the EA did not lead him to believe that there would be a significant environmental impact from the use of olestra in savory snacks. He suggested bringing the issue to closure by having Procter and Gamble provide a letter for FDA's files containing P&G's analysis of the issue. Dr. Allgood accepted that suggestion. Dr. Topper said that EPA did not need to be further involved in the review unless FDA so desired. Dr. Allgood and I thanked Dr. Topper for his time.

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Jeanette Glover Glew

Exhibit 1

We assessed the fate and effect of olestra on sediment in the olestra environmental assessment (format item 7.b.iii.3, pages 26-29, and format item 8.b.i.2, pages 34-35, respectively), and concluded that olestra will not have an adverse impact on sediment. A description of our approach is described below.

Fate of Olestra in Sediments

We assessed the fate of olestra in sediments and concluded that any accumulation of olestra in sediments will not present a concern because 1) any cumulative accumulation will not be significant, 2) olestra likely degrades anaerobically, and 3) any accumulation is not different in concept than what occurs with the fat which olestra will replace.

We used highly conservative approach for determining the potential maximum sediment concentration of olestra in sediment (Exhibit 11 of the environmental assessment). Cumulative accumulation of olestra, conservatively assuming no biodegradation of olestra and complete degradation of other organics, would result in only relatively small increases in the amount of olestra in sediment (format item 7.b.iii.3, pages 29).

We can be reasonably sure that olestra will degrade in anaerobic sediments. This is because an anaerobic digester effect study showed gas stimulation with high concentrations of liquid olestra, suggesting that olestra degrades anaerobically (Exhibit 24 of the environmental assessment). Furthermore, recent biodegradation work showed that olestra is degraded by a number of different types of microbes present in diverse environments and that the likely first step is esterase cleavage. Anaerobes exhibit esterase activity and could cleave olestra to fatty acids, which would then be slowly degraded.

Any accumulation of olestra will not be different in concept than the known behavior of fats, oils, and grease (FOG). Proton-reducing, acetogenic bacteria and hydrogen-utilizing, methanogenic bacteria establish a syntrophic interaction allowing them to degrade fatty acids by anaerobic respiration (Letter to the FDA dated August 15, 1991, Assessment of Olestra Effect on Gut Microflora, p. 21).

Exhibit 1 (cont'd)

Effect of Olestra in Sediments

We assessed the toxicity of olestra in sediments and concluded that olestra would not be toxic to organisms in sediments based on 1) EPA's equilibrium partitioning approach for predicting the toxicity to sediment organisms and 2) testing in reasonable surrogates for sediment dwelling organisms.

A conservative application of the EPA equilibrium partitioning approach predicts that the safe limit for olestra in sediments (Exhibit 17 of the environmental assessment) is above the highly conservative estimate for the maximum sediment concentration of olestra (Exhibit 11 of the environmental assessment).

Consistent with this conclusion, chronic testing of olestra in earthworms, a reasonable surrogate for benthic organisms ingesting sediment, showed no adverse effect of olestra (format item 8.b.ii.3, page 36). Furthermore, extensive long-term testing in mammalian species, as well as absence of absorption, show that olestra is essentially inert and provides assurance that chronic toxicity will not occur. The absence of toxicity and bioconcentration of olestra in a 28-day chronic bioconcentration study in fish also supports the lack of chronic toxicity (format item 7.b.iii.1, page 26).

MEMORANDUM OF TELEPHONE CONVERSATION
July 25, 1995

Between: Dr. Martin Topper
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Office of Federal Affairs
(202) 260-5051

and: Jeanette Glover Glew
FDA:CFSAN:OPA:DPMU
Environmental Impact Staff

Subject: FAP 7A3997 - Olestra

I called Dr. Topper and told him that, in FDA's letter to EPA requesting a review of the environmental assessment (EA) for olestra, FDA had requested EPA to determine whether Procter & Gamble's EA addressed the issues raised by EPA at the August 25, 1992, meeting and whether EPA agreed with our tentative finding of no significant impact (FONSI). EPA responded on June 14, 1995, that the questions raised at the August 25, 1992, meeting were addressed in a satisfactory manner, but did not specifically respond to the second part of FDA's question. I reminded Dr. Topper that, in a telephone conversation with me on June 21, 1995, he had stated that his review of the EA did not lead him to believe there would be a significant environmental impact from the use of olestra in savory snacks. I asked if I could use that statement, or a similar one, in my FONSI. Dr. Topper said that EPA would not officially make that strong a statement because the responsibility for decisionmaking would be left up to FDA. He said a more appropriate response would be that EPA did not raise any environmental objections. I asked him if I could use that statement in my FONSI and he agreed that I could do so.

/s/

Jeanette Glover Glew

